UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

December 17, 2019

MEMORANDUM:

Subject: Acute Toxicity Review for EPA Reg. No / File Symbol: 42750-GLI

Applicant:	Albaugh, LLC
Product Name:	Flucarbazone 3.0
DP Barcode:	D451466
Decision No.:	549063
Action Code:	R333
PC Code(s):	114009 (Flucarbazone-sodium)

From: Bonaventure A. Akinlosotu, PhD
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/Toxicology Team

To: Nathan Mellor/Erik Kraft, RM Team 24
Fungicide & Herbicide Branch
Registration Division (7505P)

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
Flucarbazone-sodium	35.00
Other Ingredients:	65.00
Total:	100.00

BACKGROUND:

The registrant (Albaugh, LLC) applied to register the subject proposed end-use product (EP), an herbicide containing the active ingredient Flucarbazone-sodium.

The Agency reviewed the data submitted for the six studies (MRID Nos 50786610 thru 50786615), to assess the acute toxicity, irritation, and sensitization potential of the proposed product (see Toxicity Profile – below under Findings). It was determined that these data are acceptable to support the registration of the proposed product.

The Product Chemistry data (including the basic and any alternate formulations/CSFs) must be reviewed and found acceptable by the Agency. The proposed label was screened as it pertains to the acute toxicity requirements. The final review of the labeling (uses, use directions, storage/disposal, etc.) is the purview of the RM team.

GLP: All studies were conducted in accordance with GLP.

FINDINGS, COMMENTS AND RECOMMENDATIONS:

The six studies are classified as acceptable satisfy the acute toxicity data requirements for the registration of the proposed product (EPA File Symbol 42750-GLI). The toxicology profile is as follows:

acute oral toxicity	IV	acceptable	MRID 50786610
acute dermal toxicity	IV	acceptable	MRID 50786611
acute inhalation	III	acceptable	MRID 50786612
primary eye irritation	IV	acceptable	MRID 50786613
primary dermal irritation	IV	acceptable	MRID 50786614
dermal sensitization	-ve	acceptable	MRID 50786615

PRECAUTIONARY LABELING:

Product Reg. No.: 042750-00358

Product Name: Flucarbazone 3.0

PRECAUTIONARY STATEMENTS

KEEP OUT OF THE REACH OF CHILDREN

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if inhaled. Avoid breathing spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, shoes plus socks.

First Aid*:

If inhaled:
- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

*Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Users should:
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

DATA EVALUATION RECORD

Reviewers: Bonaventure Akinlosotu, PhD **Date:** December 03, 2019
Thomas C. Marshall, PhD (Summitec Corp.)
Product Reg. No./File Symbol: 42750-GLI

1. DP BARCODE: 451466

2. PC CODES: 114009

3. CURRENT DATE: December 03, 2019

4. TEST MATERIAL: Flucarbazone 3L: Lot # FCBZ-1-2; Composition: Flucarbazone (as Flucarbazone sodium; 21.1 % w/w in water (23.7 % w/v), CAS # 181274-17-9; Liquid; pH = 5.58.

Study/Strain & Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity/ Sprague Dawley Crl: CD®(SD)IGS-BR rat Microquim S.A. (Buenos Aires, Argentina Study No. BI-120516, MU 88135 January 24, 2019 OCSPP 870.1100	50786610	**LD_{50} in females >5000 mg/kg bw** The test material (5000 mg/kg bw) was administered in water, to 3 fasted female rats. There were no deaths and the clinical signs for up to 4 hours after treatment were lethargy, lordosis, and excessive salivation. All animals gained weight. No treatment-related effects were noted at necropsy.	IV	A
Acute dermal toxicity/Sprague Dawley Crl: CD®(SD)IGS-BR rat Microquim S.A. (Buenos Aires, Argentina Study No. BI-120517, MU 88135 January 23, 2019 OCSPP 870.1200	50786611	**LD_{50} > 5000 mg/kg bw (both sexes)** The test material was applied (moistened as received) to the skin of 10 (5/sex) rats for 24 hours. There were no deaths and no observable clinical signs. There were no signs of dermal irritation and no observable treatment-related effects at necropsy. All rats gained weight during the study.	IV	A
Acute inhalation toxicity/ Sprague Dawley Crl: CD®(SD)IGS-BR rat (4hr, Nose-only) Microquim S.A. (Buenos Aires, Argentina Study No. BI-120518, MU 88135 January 23, 2019 OCSPP 870.1300	50786612	**LC50 > 1.08 mg/L (both sexes)** Average MMAD and GSD: 2.19 µm (2.23, 2.15 µm) and 2.39 (2.43, 2.35), respectively. The test material was nebulized as received. The exposure concentration was 1.08 mg/L (the maximum attainable concentration due to physical-chemical properties of the test substance). 10 rats (5/sex) were exposed for 4 hours.	III	A

		No deaths or observable clinical signs. Body weight loss was observed in both sexes on the day after exposure, but body weight increased thereafter. No gross treatment-related effects were noted during necropsy.		
Primary eye irritation / Albino rabbit Microquim S.A. (Buenos Aires, Argentina Study No. BI-120520, MU 88135 January 24, 2019 OCSPP 870.2400	50786613	**Minimally Irritating** **MMTS = 8.0 at 1 hour** The test material (0.1 mL) was instilled as received into the conjunctival sac of one eye of 3 female rabbits. There were no corneal or iridial effects noted in any treated eye. Minimal conjunctival irritation was noted in all treated eyes up to one hour after instillation. The eyes of all rabbits appeared normal by the 24-hour examination. No clinical signs of toxicity were noted.	IV	A
Primary dermal irritation / Albino rabbit Microquim S.A. (Buenos Aires, Argentina Study No. BI-120519, MU 88135 January 23, 2019 OCSPP 870.2500	50786614	**Non-irritating (PDII = 0.0)** The test material (0.5 mL) was applied as received to the skin of 3 female rabbits for 4 hours. No dermal reactions and no observable clinical signs of toxicity.	IV	A
Dermal sensitization/ Buehler/ Albino guinea pigs Microquim S.A. (Buenos Aires, Argentina Study No. BI-120521, MU 88135 January 23, 2019 OCSPP 870.2600	50786615	**Not considered a skin sensitizer** 30 guinea pigs (18 females, 12 males) were used in the main study (6 females, 4 males) as naive controls, and 20 treated (12 females, 8 males). A historical positive control study (October 2018) using α-hexylcinnamaldehyde (HCA) was provided. Based on a preliminary study, the test substance was applied as received (100%). All animals survived; No observable skin reactions at 24 and 48 hrs in test item- treated or control animals. <u>Positive Controls:</u> 14/20 rabbits exhibited a positive reaction at 24 hours and 5/20 at 48 hours after patch removal.	-ve	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap W = Waived